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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|---------------------|------------------|
| 09/259,389 | 02/26/1999 | KATIA GEORGOPoulos | 10287/043001 | 5245 |
| 26161 | 7590 | 03/08/2005 | EXAMINER | |
| FISH & RICHARDSON PC | | | WOITACH, JOSEPH T | |
| 225 FRANKLIN ST | | | | |
| BOSTON, MA 02110 | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-------------------|--------------|--------------|
| Application No. | 09/259,389 | Applicant(s) | GEORGOPoulos |
| Examiner | Joseph T. Woitach | Art Unit | 1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 October 2004.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2,5,10,11,13,21 and 25-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 2,5,10,11,13,21 and 25-38 is/are allowed.

6) Claim(s) 39-42 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 2/26/1999 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

This application filed March 26, 1999, claims benefit to provisional application 60/076,325, filed March 27, 1998.

Applicants' amendment filed October 6, 2004, has been received and entered. Claims 1, 3, 4, 6-9, 12, 14-20 and 22-24 have been canceled. Claims 10, 11, 13, 26 have been amended. Claims 29-42 have been added. Claims 2, 5, 10, 11, 13, 21 and 25-42 are pending and currently under examination.

Claim Objections

Claim 41 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. While the claim only sets forth one hybridization condition, it fails to set forth a washing condition commensurate in scope with the independent claims because it omits the temperature at which washing occurs, broadening the dependent claim.

Claims 41 and 42 are objected to because of the following informalities: the claims should be amended to read (for example) "The nucleic acid of claim 39 or 40 that hybridizes" to be more grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 11 and 13 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons below and set forth in the previous office action is withdrawn.

The amendment to the claims to cancel claim 3 and amend the remaining claims to depend on previously allowed claims has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 41 fails to further limit claims 39 and 40 because it does not set forth a specific washing temperature, thus broadens the scope of the claim. Further, without a specific temperature, the claim is indefinite because it is open to relative nature of what one would consider “high stringency conditions”.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 40 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 39. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In this case the slight difference in the wording of the preamble does not distinguish a difference in breadth of the claims, in particular because each must hybridize to SEQ ID NO: 5 and the same buffer conditions are recited in the body of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 39-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Hahm *et al.*

Hahm *et al.* disclose the *Mus musculus* helios mRNA sequence which share high homology to SEQ ID NO: 5. In light of the high homology with the sequence taught by Hahm

et al. and the breadth of the claims to encompass only the particular hybridization conditions and washing conditions without any specific time for any of these steps conditions, the sequences of Hahm *et al.* would be identified by SEQ ID NO: 5. While “high stringency conditions” are claimed and specific conditions are set forth in the claim, the claims are very broad because critical features of hybridization such as volumes of buffers, times of incubation, and length of time of and means used to determine hybridization are not set forth in the claims.

Conclusion

As indicated previously, claims 2, 5, 21 and 25-26 were allowed. Claims 10, 11 and 13 have been amended as suggested in the previous office action and are allowed. Newly added claims 29-38 encompass SEQ ID NOS: 2 and 4, which are free of the art of record. It is noted that while the sequences are highly homologous to those disclosed in Hahm *et al.* they are not exactly the same, for example the second difference between the sequences the SEQ ID and that of Hahm *et al.* results in codons that encode a different protein sequence (see homology search results). Claims 2, 5, 10, 11, 13, 21, 25-38 are free of the art of record because the art fails to teach the polynucleotide sequences which would anticipate the present claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

J. T. Woitach
AU 1632